

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-12 NEA-10 ISO-00 OES-07
EB-08 COME-00 /070 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/PAN:JBECKER(INFO)
ARA/AND/E:JALLITTO(INFO)
EA/PHL:KBLEAKLEY(INFO)
EA/TIMBS:LROCKE,JR(INFO)
NEA/IAI:WSMITH,II(INFO)
EUR/NE:WNEWLIN(INFO)
ARA/CEN:DJOHNSON(INFO)
NEA/IRN:MGREENE (INFO)
ARA/AND/V:WSERGEANT (INFO)
EUR/NE:JSHUMATE (INFO)
EA/J:EDEATHERSTONE (INFO)
EA/TIMBS:MEASTON (INFO)

-----123914 131559Z /53

P 131429Z APR 78
FM SECSTATE WASHDC
TO AMEMBASSY PANAMA PRIORITY
AMEMBASSY QUITO PRIORITY
AMEMBASSY MANILA PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY SAN JOSE PRIORITY
AMEMBASSY TEHRAN PRIORITY
AMEMBASSY CARACAS PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY SINGAPORE PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, PN, EC, RP, TH, IS, BE, CS,
IR, VE, UK, JA, SN

SUBJECT: FDA ADVISORY - POSSIBLY DEFECTIVE STERILE LATEX
GLOVES (RECALL T-076-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED: TRAVENOL TRIFLEX LATEX STERILE GLOVES,

ALL SIZES, EACH TYPE DIRECTED FOR THEIR SPECIFIC USE BY THEIR LABELING IDENTIFICATION.

2. PRODUCT IDENTIFICATION: A) TRAVENOL TRIFLEX STERILE LATEX SURGEON'S GLOVES; ALL SIZES; MARKETING BY TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS 60015, IN BLISTER PACK, PRODUCT CODE

2D7140: ALL LOTS LESS THAN NG45L6
2D7141: ALL LOTS LESS THAN NG47P3A
2D7142: ALL LOTS LESS THAN NG43X9
2D7143: ALL LOTS LESS THAN NG45X8
2D7144: ALL LOTS LESS THAN NG45A4
2D7145: ALL LOTS LESS THAN NG45N6
2D7146: ALL LOTS LESS THAN NG44N6
2D7147: ALL LOTS LESS THAN NG40N4
2D7100/2D7106: ALL LOTS GREATER THAN NG29L2

3. IN PEEL PACK, PRODUCT CODE 2D7110/2D7117: ALL LOTS GREATER THAN NG29L2

2D7150: ALL LOTS LESS THAN NG44N1
2D7151: ALL LOTS LESS THAN NG44S4
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2D7152: ALL LOTS LESS THAN NG44P4
2D7153: ALL LOTS LESS THAN NG43X4, PLUS NG44L7, NG44NO
2D7154: ALL LOTS LESS THAN NG44S1
2D7155: ALL LOTS LESS THAN NG43W5
2D7156: ALL LOTS LESS THAN NG44P2
2D7157: ALL LOTS LESS THAN NG39X4

4. B) TRAVENOL TRIFLEX LATEX PROCEDURE GLOVES, STERILE, DISPOSABLE, ALL SIZES; MARKETING BY TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS 60015; PRODUCT CODE:

2D7122: NG29L1/NG47A3, NG49N3
2D7123: NG29L1/NG48F9, NG49L2
2D7124: NG29L1/NG48N3, NG48R3, NG48W1, NG51F9
2D7125: NG29L1/NG45F1, NG46X1, NG48L2

5. C) TRAVENOL TRIFLEX LATEX EXAMINATION GLOVES, STERILE, DISPOSABLE, ONE PAIR; ALL SIZES; MARKETING BY TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS 60015; PRODUCT CODE: 2D7036: NG40R8/NG48S8

6. D) TRAVENOL TRIFLEX LATEX EXAMINATION GLOVE, STERILE, DISPOSABLE, SINGLE GLOVE; ALL SIZES; MARKETING BY TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS 60015; PRODUCT CODE: 2D7025: NG31R8/NG48PO
2D7026: NG31W9/NG49N6, NG49W0
2D7027: NG31R9/NG48S2

7. E) BULK GLOVES SOLD TO INDUSTRIAL ACCOUNTS FOR REPACKING

PRODUCT CODE: LOT NUMBERS:

2Y1004 EG03R7, EGO3R6, EGO4A2

2Y1005 EG05R3, EG05R5

2Y1116 N03X0, KL82B, EGO1P0, NO3S4 ,

2Y1118 N03P1-1, N03S4-29, N03R2, N03X0, EGO1P1,

2Y1117 EG01N9, N03X0, N03S4, KL82C

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2Y1119 N03R2, N03S4, KLO1S1-2, EGO1P2, N03X0, N0359-3

2Y1120 EGO1P3, KLO1S1, N03S2

2Y1121 EGO1P4, N03S2, KLO1S1

2Y1122 EGO1S2, N03P1-7, N03S4, N03X0, KL82B

2Y1123 N03P1-7, N03S4, N03X0, KL82F

8. F) STERILE LATEX SURGEONS GLOVES - MILITARY ACCOUNTS

PRODUCT CODE: LOT NUMBER:

2D7587V NG33A3/NG33A9

2D7588V NG33H9/NG34A3

2D7589V NG33A4/NG34A2

2D7590V NG33F7/NG33W9

2D7591V NG30S9/NG33A7

2D7586 NG31A2, NG31WO

2D7587 NG36F9/NG38S4

2D7588 NG35X7/NG38A7, NG38H3/NG42RO

2D7589 NG41R6, NG41R8, NG41S2, NG41S5, NG42L4

2D7590 NG40F7/NG42S2

ALSO, THE RECALLED GLOVES WERE PACKED IN THE FOLLOWING
KITS AND TRAYS:

9 G) TRAVENOL STERILE DISPOSABLE SKIN SCRUB TRAY; TRAVENOL
LABORATORIES INC., DEERFIELD, ILLINOIS 60015; CATALOG
NO. 2D2105; ALL LOTS PRIOR TO G126L6

10. H) TRAVENOL DISPOSABLE URETHRAL CATHETERIZATION TRAY
WITH 16 FRENCH CAHTETER-WITH AN IODOPHOR AND LARGE SIZE
GLOVE; TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS
60015; CATALOG NO. 2D2974; GLOVE LOT NUMBER G125W8 AND
G125W9

11. I) TRAVENOL DISPOSABLE FOLEY CATHETERIZATION TRAY WITH
18 FRENCH CATHETER - WITH AN IODOPHOR AND LARGE SIZE
GLOVE; TRAVENOL LABORATORIES, INC., DEERFIELD, ILLINOIS
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60015; CATALOG NO. 2D2975, GLOVE LOT NUMBER G124RO

12. J) TRAVENOL SERVIPAK ANCILLARY SUPPLIES KIT; ARTI-
FICIAL ORGANS DIVISION, TRAVENOL LABORATORIES, INC.,
DEERFIELD, ILLINOIS 60015; CATALOG NO. 5M2259, BEC-2;

ALL LOTS OF KITS CONTAINING GLOVE CODES 2D7025, 2D7026, 2D7027, 2D7123, 2D7124, 2D7125, 2D7111, AND 2D7112. LOT NUMBERS ARE LISTED IN A, B, D ABOVE.

13. MANUFACTURERS: TRAVENOL LAORATORIES, INC., HIGHWAY 52, NORTH, KINGSTREE, S.C. 29556 AND TRAVENOL LABORATORIES INC., DAYTON FLEXIBLE PROD. DIV., EATON, OHIO. NOTE: ALL RECALLED GLOVES WERE ETO STERILIZED AT THE KINGSTREE PLANT.

14. REPACKERS: TRAVENOL LABORATORIES, INC., CLEVELAND, MISSISSIPPI: REPACKS GLOVES INTO SKIN SCRUB TRAYS AND CATHETERIZATION TRAYS. TRAVENOL LABORATORIES, INC., MORTON, GROVE, ILLINOIS: REPACKS GLOVES INTO SERVIPAK KITS.

15. RECALLING FIRM: TRAVENOL LABORATORIES, INC., ONE BAXTER PARKWAY, DEERFIELD, ILLINOIS 60015.

16. REASON FOR RECALL: A CHANGE IN LATEX FORMULATION HAS RESULTED IN A DECREASE IN TENSILE STRENGTH OF THE GLOVES WITH AGE (ABOUT 3 MONTHS) AFTER ETO STERILIZATION. THE NEW LATEX FORMULATION, DESIGNATED PLDF-69, OR "KINGSTREE FORMULATION" WAS FIRST USED ON MAY 24, 1976, AND USAGE CONTINUED TO OCTOBER 21, 1977. THE FIRM BECAME AWARE OF THE PROBLEM IN EARLY 1977 AS A RESULT OF COMPLAINTS FROM THE USER LEVEL. THEIR INVESTIGATION INDICATED THE NEW LATEX FORMULATION WOULD NOT WITHSTAND AN ETHYLENE OXIDE STERILIZATION CYCLE ADEQUATE TO STERILIZE THE PRODUCT. SOME OF THE GLOVES OF THE NEW LATEX FORMULATION WERE RADIATION STERILIZED AND ARE NOT SUBJECT TO THE RECALL.

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17. THE FIRM HAS RECEIVED HUNDREDS OF COMPLAINTS FROM JULY 1977 TO THE PRESENT REGARDING DEFECTS SUCH AS PIN HOLES, LARGE HOLES, THIN SPOTS, TEARS, ROUGH TEXTURE, AND SPOTTY OR BLOTCHY APPEARANCE. SEVERAL COMPLAINTS REPORTED SKIN REACTIONS, AND ONE HOSPITAL, KINGS DAUGHTERS HOSPITAL, TEMPLE, TEXAS, INDICATED A HIGHER POST-OP INFECTION RATE. TRAVENOL FAILED TO CONDUCT STABILITY AND AGING STUDIES ON THE GLOVES MADE WITH THE LATEX FORMULATION

18. TRAVENOL MAILED RECALL LETTERS DATED 2-24-78 VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED, ON 2-24 AND 25, 1978 TO ALL GLOVE CUSTOMERS.

19. HOLD NOTICES WERE PREVIOUSLY ISSUED TO DISTRIBUTION CENTERS. THE RECALL LETTER INSTRUCTED THE CONSIGNEE TO DISCONTINUE USE OF THE RECALLED PRODUCT AND RETURN IT TO TRAVENOL, KINGSTREE. THEY WERE ALSO INSTRUCTED TO COMPLETE THE ENCLOSED INVENTORY SHEET AND RETURN IT TO TRAVENOL, DEERFIELD. DEALERS WERE INSTRUCTED TO SUB-

RECALL. TRAVENOL'S GOVERNMENT CONTRACT MANAGER TELEPHONED
MILITARY AND V.A. COORDINATORS 2-24, 27 -78 ADVISING THEM
OF THE RECALL.

20. LETTERS WERE SENT TO THESE ACCOUNTS ON 3-2-78, WITH
FOLLOW-UP LETTERS TO FOLLOW.

21. RECALL LETTERS DATED 3-6-78 UNDER THE DAYTON FLEXIBLE
-ETTERHEAD WERE SENT TO THE 4 INDUSTRIAL ACCOUNTS, INSTR-
UCTING THEM TO RETURN THE LISTED RECALLED LOTS OF PRODUCTS

TO TRAVENOL, KINGSTREE. THE ACCOUNTS WERE INSTRUCTED TO
SUB-RECALL ANY OF THE RECALLED GLOVES WHICH THEY HAD
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REPACKED AND SOLD. ALSO, THEY WERE INSTRUCTED TO COMPLETE
AND RETURN AN ENCLOSED ATTACHEMENT WHICH ACCOUNTED FOR
ALL LOTS OF RECALLED GLOVES RECEIVED BY THE INDUSTRIAL
ACCOUNT.

22. IMPORTANT DEVICE INFORMATION LETTERS DATED MARCH 6,
1978 WERE SENT TO ALL CONSIGNEES RECEIVING THE SKIN SCRUB
TRAYS, CATHETERIZATION TRAYS, AND SERVIPAK KITS. THESE
LETTERS NOTIFIED THE ACCOUNTS OF THE PROBLEM WITH THE
GLOVES. TRAVENOL SENT 50 PAIRS OF REPLACEMENT GLOVES
WITH THE SERVIPAK LETTERS. TRAVENOL THEN ISSUED RECALL
LETTERS DATED 3-16-78 TO THE SAME CONSIGNEES INSTRUCTING
THEM NOT TO USE THE GLOVES IN THE TRAYS AND KITS, BUT TO
DISCARD THEM AND REPLACE THEM FROM NORMAL INVENTORY.
RETURN REPLY CARDS WERE INCLUDED. DEALERS WERE INSTRUCTED
TO RETURN GLOVES FROM SKIN SCRUB TRAYS ON HAND IN INVEN-
TORY AND TO NOTIFY ANY ACCOUNTS RECEIVING THE TRAYS OF
THE RECALL.

23. CERTAIN INTERNATIONAL RECIPIENTS WERE NOTIFIED BY
DISTRIBUTION OF INTER-OFFICE MEMORANDUM FROM A MR. T.
RUSSILLIO

24. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED INFORMATION MEMORANDUM
OF 3-1-78 REGARDING U.S. RECALL. ANY QUESTIONS SHOULD
BE REFERRED TO MR. T. RUSSILLO OF TRAVENOL.

25. FOREIGN CONSIGNEES AS FOLLOWS:
DEPOSITO MEDICO DENTAL S.A.
APARTADO 4004
PANAMA CITY PANAMA

HOSPITAL MILITAR
LADRON DE GUEVARA
QUITO ECUDOR
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PACIFIC BIO-MEDICAL SUPPLIES
(DISTRIBUTOR)
P.O. BOX S
AGANA, GUAM

F.V.A. EX-IM TRADING INC.
3RD FLOOR SARMIENTO BLDG.
6782 AYALA AVE.
MAKATI BIZAL, PHILIPPINES

THORNBURI HOSPITAL
BANGKOK, THAILAND TRAV TRADING CO. LTD.
-- ASHDOD, ISRAEL

S.A. TRAVENOL LABORATORIES N.V. INDUSTRIAS QUIMICAS S.A.
BOULEVARD D. HOURAING DISTRIBUTORS
7860 LESSINES BELGIUM APARTADO 10178
-- SAN JOSE COSTA RICA, CA

CAJA DE SEQURO SOCIAL IMPORTADORA SCHILLER C
APARTADO 1393 DISTRIBUTOR
PANAMA 1 REP DE PAN GARCIA 512 Y ALMAGRO
-- APT. 2716
AMCO PHARMA CC LTD. QUITO ECUADOR
DISTRIBUTOR
PHATRA THANAKIT BLDG. MEDICAL PRODUCTS, INC.
2ND FLOOR SIBUEN STREET NO. 7
183 SUKHUMVIT ROAD TEHRAN, IRAN
BANGKOK, THAILAND
-- TRAVENOL LABORATORIES LTD
LABORATORIOS BAXTER CA CAXTON WAY THETFORD
APDO 68739 ZONA 106 NORFOLK ENGLAND
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CARACAS VENEZUELA
-- IMPORTADORA SCHILLER C
INDUSTRIAS QUIMICAS S.A. GARCIA 512 Y ALMAGRO
APARTADO 10178 APARTADO 2716
SAN JOSE, COSTA RICA CA QUITO, ECUADOR

EXECUTIVE TRADERS AND MGRS. GRP
GROUND FLOOR OMEGA 1 SALCEDO 40 2-CHOME DOSHOMACHI
LEGASCI VILLAGE MAKATI METRO HIGASH-KU
MANILA PHILIPPINES OSAKA, JAPAN

TRAVENOL LABORATORIES PTE LTD
SHAW CNTR SCOTTS RD
SUITE 1705
SINGAPORE 9

MALAYSIA CHRISTOPHER

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Message Attributes

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Channel Indicators: n/a
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Copy: SINGLE
Draft Date: 13 apr 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Handling Restrictions: n/a
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ISecure: 1
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Litigation Codes:
Litigation History:
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Subject: FDA ADVISORY - POSSIBLY DEFECTIVE STERILE LATEX GLOVES (RECALL T-076-8)
TAGS: OGEN, ETRD, EIND, TBIO, PN, EC, RP, TH, IS, BE, CS
To: PANAMA QUITO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/b037bda6-c288-dd11-92da-001cc4696bcc
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